IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

: 10/555,470

Applicant

: Roger R. Dzwonczyk et al.

Filed

: 11/02/2005

Tech. Center/Art Unit

: 4123

Examiner

: Michael C. Stout

Attorney File No.

: OSU GEN 2949 PCT US

Customer No.

: 002555

Confirmation Number

: 4111

For

: Measuring Human Heart Muscle Viability Using

Myocardial Electrical Impedance

I hereby certify that this correspondence is being transmitted via the Office Electronic Filing System (EFS)

on <u>27</u>

2009.

DECLARATION OF ROGER R. DZWONCZYK

I, Roger R. Dzwonczyk, declare as follows:

- 1. I am one of the joint or co-inventors named in the above identified patent application;
- 2. I am a joint or coauthor of the two publications that have been cited by the examiner, are referred to herein as paper A and paper B and are identified as follows:
 - A. R. Dzwonczyk et al. "Myocardial Electrical Impedance Responds to Ischemia and Reperfusion in Humans", *Computers in Cardiology* 2002;29:541-543. Paper A was both cited and applied in a rejection by the examiner.
 - B. CL delRio et al. "Use of Myocardial Electrical Impedance to Assess the Efficacy of Preconditioning", *Computers in Cardiology* 2002;29:489-492. Paper B was cited but not applied by the examiner.

- 3. The policies governing authorship of a publication have been established by the editors and publishers of the scientific journals. Scientists and engineers are ethically bound to follow these policies. Authorship on scientific papers is customarily determined in the scientific community by including as authors all workers who have made significant contributions to the design, conduct, analysis and/or the data interpretation of a scientific experiment. An individual can be a co-inventor but not participate in an experiment that involves the invention. Then by policy that individual should not be included as a co-author. Similarly, an individual can be a co-author in an experiment because he/she contributed to the design, conduct and interpretation of an experiment but did not contribute to the invention disclosed and claimed in the patent application.
- 4. Paper A was first published on September 22, 2002. It was first distributed to interested members of the public by its inclusion in the proceedings for a meeting held in Memphis, Tennessee on September 22-25, 2002 under the title Computers in Cardiology. Paper A was presented by me at that meeting. The proceedings is a collection of papers that were to be presented at the meeting. A copy of a portion of the distributed proceedings was submitted with my previously submitted declaration.
- 5. Paper A is a publication by the applicants in the above patent application themselves. The paper has six named authors. Three of the authors are co-inventors of the invention described and claimed in the patent application. The other three authors, Drs. Brown, Michler and Wolf, are the cardiothoracic surgeons who performed the revascularization surgery from which data was obtained. They are coauthors on the publication because they gave me the opportunity to measure MEI on their patients in the operating room and helped me accomplish that. Including them as coauthors is an appropriate thing to do in the scientific community.

They are not, however, co-inventors and did not contribute to the invention described and claimed in the above identified patent application. The three surgeons were merely working under my direction with respect to the data collection and subject matter of the invention.

6. Paper B was first published on September 22, 2002 and was first distributed to interested members of the public by its inclusion in the same proceedings for the same meeting described above with reference to paper A.

7. Paper B is also a publication by three of the applicants in the above patent application themselves and four additional coauthors. The paper has seven named authors. Three of the authors are co-inventors of the invention described and claimed in the patent application. The coauthors and the roles of the non-inventors in the experiment were as follows:

del Rio - Co-inventor.

Dzwonczyk – Co-inventor.

Clymer – Electrical engineering advisor to del Rio in PhD program. Examined methods of analyzing the MEI data.

McSweeney – Surgeon who contributed to the conduct of the study.

Awad – Anesthesiologist in the study.

Czerwinski – Assisted in surgery as surgeon and anesthesiologist.

Howie - Co-inventor.

The four coauthors, who are not co-inventors, were working under my direction with respect to the data collection and subject matter of the invention described and claimed in the above identified patent application.

8. Although Patrick McConnell is a co-inventor of the invention described and claimed

in the above identified patent application, he did not play a significant enough role in the

experiments which were the subject of the papers to justify his inclusion as a co-author of the

papers. The invention described and claimed in the above identified patent application was

conceived by the named four co-inventors by collaboration among them in discussions during

the course of meetings at which they were personally present at The Ohio State University in

Columbus, Ohio USA. These meetings occurred more than six years ago and therefore it is

impossible to have a clear recollection of who made what suggestions. To the best of my

knowledge and belief the co-inventors of the invention described and claimed in the above

described patent application each made an approximately equal contribution to the subject

matter of the claims in the patent application. To the best of my knowledge and belief none of

the co-inventors made no contribution to any of the claims. Patrick McConnell contributed

equally to the invention as disclosed and claimed in the above identified patent application.

The undersigned, being hereby warned that willful false statements and the like are

punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false

statements may jeopardize the validity of the application or any resulting patent, declares that

all statements made in this declaration of his/her own knowledge are true; and all statements

made in this declaration on information and belief are believed to be true.

Date of Signature

oger R. Dzwonczyk

I:\client.docs\o\ohio state university - osu\gen 2949 heart viability dzwonczyk\us\docs for response to final oa of 4-8-09\declaration of dzwonczyk revised.doc

Last printed 4/30/2009 11:57 AM